



Food and Drug Administration  
Detroit District  
1560 East Jefferson Avenue  
Detroit, MI 48207-3179  
Telephone: 313-226-6260

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

WARNING LETTER  
99-DT-14

September 14, 1999

Mr. Dennis Bielecki  
Radiology Manager  
St. Mary Hospital  
36475 Five Mile Rd.  
Livonia, MI 48154

Dear Mr. Bielecki:

Your facility was inspected on August 25, 1999 by a representative of the State of Michigan, acting in behalf of the Food & Drug Administration (FDA). The inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal regulations (CFR), Part 900.12, as follows:

Evaluation of the mammography quality control (QC) records revealed that the required weekly phantom evaluations had not been accomplished for nine (9) weeks for both Room 1 and Room 2. The quality standard for mammography requires that facilities perform an image evaluation test using an FDA approved phantom, at least weekly, and that mammography exams be suspended until a satisfactory phantom image is obtained. [21 CFR Part 900.12(e)(2)]

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. The deficiency may be symptomatic of serious underlying problems that could compromise the quality of the mammography at your facility.

In addition, the following deficiency appeared under the noncompliance Level 2 heading on your MQSA Facility Inspection Report. Five (5) of ten (10) random medical reports that were reviewed did not contain an assessment category as specified under 21 CFR 900.12(c)(1)(iv).

Within 15 working days after receiving this letter, you should notify the FDA in writing of:

- the specific steps you have taken to correct the Level 1 and 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of the deficiencies that the inspection identifies and promptly indicate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

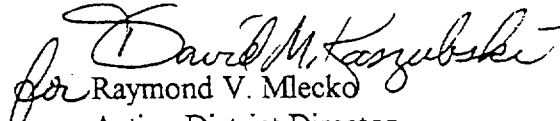
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed. Please send the original copy of your response to Mr. David M. Kaszubski, Compliance Officer, U.S. Food & Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207. Also send a copy to the State of Michigan radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

  
for Raymond V. Mlecko  
Acting District Director  
Detroit District

Enclosures: a/s